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EXAMINER

GILBERT, SAMUEL G

ART UNIT PAPER NUMBER

3735

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,962

Applicant(s)

ALFERNESS ET AL.

Examiner

Samuel G. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 22, 23, 25, 26, 28, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 37 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2/13/2006 has been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18, 19, 22, 23, 28 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Wanat et al (5,839,842). The examiner is taking only jacket –2- of the entire kit of Wanat et al to meet the claims as set forth below.

Claims 18, 23, and 28 – element –2- forms a jacket, the jacket has an open end shown at –6-, and the jacket may be formed from polyethylene, a biocompatible material. The diamond pattern allows for differential expansion of the jacket with the diamond pattern oriented as shown in figure 1. It is the examiner's position that the jacket of Wanat et al is with the diamond pattern oriented as shown is inherently capable of performing the

other functions set forth in the functional language of the claim. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The claim was amended to include "shaped", it is the examiner's position that tubular mesh bags assume the shape of whatever is placed inside of them therefore meets the limitation of being shaped to snugly conform to an external geometry of the heart. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the knit construction. It is also the examiner's position that the mesh structure of Wanat provides the same functional limitation.

Claim 19 – the examiner is taking each leg of the diamond pattern as elongated members.

Claim 22 – the jacket is configured to constrain at least a lower portion of the heart.

Claim 35 – the jacket includes a closed end.

Claims 18, 19, 22, 23, 26, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Field (1,682,119).

Claims 18, 22, 23, and 28 – metallic envelope –2- is a jacket, both ends of the envelope are open and both ends may be selectively closed. German silver may be used for the jacket and German silver is biocompatible. The material pattern shown in figure 3 and arranged as shown in figure 1 provides for a jacket having the particular expansion properties as claimed in the functional language set forth in the claims. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The shape of the envelope -2- will be determined by what is placed in the envelope further the material pattern allows for the shape to be adjusted. The interconnected rows of hinges provide for expansion and contraction in the circumferential direction without affecting the length of the envelope. Therefore it is the examiner's position that if placed on a heart the expansion properties of Field will be as claimed by the applicant. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For

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example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Field.

Claim 19 – elongate members form cells as shown in figure 3.

Claim 26 – the members may be silver.

Claims 34 and 35 – the jacket as taught by Filed has open ends that are selectively closed by elements –3-. Before either end is closed the jacket has two open ends and after one end is closed and before the second end is closed the jacket would have one open end and one closed end.

Claims 18, 19, 22, 23, 28 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mercer et al (3,551,543).

Claim 18, 22, 23, 28, and 29 – a jacket is set forth by the tubular net, column 4 lines 63 and 64. The tubular net inherently has two open ends and the net is specifically designed to have differential expansion properties wherein the jacket is more readily expandable in the longitudinal direction than in a direction traverse to the longitudinal direction. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The shape of the tubular net will be determined by what is placed in the

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envelope further the material pattern allows for the shape to be adjusted. The specific design of the mesh pattern determines expansion and contraction in the circumferential direction and longitudinal direction. Therefore it is the examiner's position that if placed on a heart the expansion properties of Mercer et al will be as claimed by the applicant.

Further, the applicant's attention is directed to paragraph [0058] of the applicants

specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Mercer et al.

Claim 19 – elongated members are set forth in elements –1-, -2- and –3-.

Claim 34 – the tubular net inherently has two open ends.

Claims 18, 19, 22, 23, 25, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehler(2,376,442).

Claims 18, 23, and 28 – element –10- forms a jacket, the jacket may be knotted at –11- and –12- therefore either or both ends may be open or closed. The diamond pattern

allows for differential expansion of the jacket with the diamond pattern oriented as shown in figure 1 which is inherently capable of performing the other functions set forth in the functional language of the claim. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The specific material to make the netting is not set forth, however it appears that the material would be the same as used for other fish netting devices as described in column 1. Matheson(4,466,331) lists a variety of materials well known in the net making art used for making fish nets, column 1 lines 53-59.

Polyethylene is a well-known material in the net-making arts, therefore it is clear to one of ordinary skill in the art in the absence of any specific guidance in Mehler itself that polyethylene may be selected to make the net of Mehler. The examiner is taking polyethylene to be a biocompatible material. The specific design of the mesh pattern determines expansion and contraction in the circumferential direction and longitudinal direction. Therefore it is the examiner's position that if placed on a heart the expansion properties of Mehler et al will be as claimed by the applicant. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S"

(FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole.” Therefore it is the examiner’s position that “shaped” as claimed represents a functional limitation provided for by the construction of Mehler.

Claim 19 – the examiner is taking each leg of the diamond pattern as elongated members.

Claim 22 – the jacket is configured to constrain at least a lower portion of the heart.

Claim 25 a plurality of fibers are used, applicant’s attention is invited to Figure 2.

Claim 34 – the ends –11- and –12- are open before they are closed.

Claim 35 – the jacket includes a closed end –11- or –12-.

Allowable Subject Matter

Claims 24 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

With regard to Wanat the applicant argues the claim has been amended to include “shaped to snugly conform to an external geometry of the heart. It is the examiner’s position that the mesh structure of Wanat inherently will snugly conform the material inside the mesh structure as this is the general nature of mesh material.

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Further, the applicant argues that the expansion properties in response to a force applied by a heart is not set forth in Wanat. It is the examiner's position that this language is directed to an intended use of the device and that Wanat is not required to teach a heart providing a force to the bag only a device capable of providing the response. It is the examiner's position that the diamond pattern provides this response.

It is the examiner's position that the recited intended use and functional language set forth in the claim has not provided any structural differences between the claimed invention and the device of Wanat et al.

With respect to Mercer, the applicant argues that the net of Mercer can expand in one direction, but cannot expand in a direction traverse to that direction. The Examiner disagrees, Mercer teaches more expansion in one direction and less expansion in the other direction. In the lines cited by the applicant Mercer does not indicate that the net "cannot" expand in any direction. Further, even if Mercer did indicate that the net could not expand in one direction and could expand in the other direction that would read on the claims as set forth because no expansion is an amount of expansion. Force applied by the heart is an intended use limitation and the device of Mercer is capable of performing as recited. Regarding the "shape" requirement, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the

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heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Mercer.

It is the examiner's position that the applicant has not set forth any specific shape to snugly conform to the heart rather the shape is "adjusted to conform as set forth in paragraph [0058], therefore the examiner believes the shapes of the cited references meet the claimed limitation.

Allowable Subject Matter

Claims 36 and 37 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

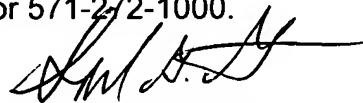
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg